1.0 PURPOSE

The purpose of this document is to establish the procedure to appropriately handle biospecimens for the AIDS and Cancer Specimen Resource (ACSR).

2.0 SCOPE

This standard operating procedure (SOP) describes how blood and tissue biospecimens should be accessioned and stored. This SOP applies to all personnel from ACSR Regional Biospecimen Repositories (RBRs) that are responsible for handling biospecimens. The AIDS Cancer Specimen Resource Regional Biorepositories and affiliates process and bank biospecimens under site specific approved Human Subjects Protocols. Biospecimens, Samples, Aliquots and Derivatives are entered into the ACSR database when consent for banking and research use have been verified by the Protocol PI or ACSR designee. Each RBR and affiliate site is responsible for Human Subjects compliance as per their institutional guidelines and their local approved Human Subjects Protocol. The SOP does not cover detailed safety procedures for handling biohazardous material and it is recommended that personnel follow institutional biosafety guidelines.

3.0 REFERENCE TO OTHER ACSR SOPS OR POLICIES

ACSR SOP Tech002 Solid Tissue Collection

ACSR SOP Tech003 Oral Biospecimen Processing and Storage

ACSR SOP Tech004 HPV Biospecimen Processing

ACSR SOP Tech005 Blood Products Body Fluids Collection

ACSR SOP Tech006 Live Tissue Collection

ACSR SOP Tech010 Biospecimen Labeling

4.0 DEFINITIONS

Term/Acronym	Definition
ACSR	AIDS and Cancer Specimen Resource
ACSR Management	ACSR staff designated by their official job title and descriptions as a Principal Investigator, Manager or Director.
Aliquot	The sample has the original characteristics of the original or parent specimen but in smaller quantities (FFPE block vs unstained

	sections from the FFPE block)
Assessment	The gathering of information on the condition of a process or activity for evaluation of such.
Biospecimen	Human material such as urine, blood, tissue stored in a biorepository for use in laboratory research. For the ACSR this is considered the original or parent biospecimen.
Calibration	Set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards (Values Indicated by Measuring).
Competence	An individual's demonstration of knowledge of key concepts, ability to apply knowledge and skills, or adequately perform a task.
Conformity	Fulfillment of a requirement, or compliance with a set standard.
Corrective action	Action to eliminate the cause of a detected nonconformity or other undesirable situation; **NOTE 1:** There can be more than one cause for a nonconformity; **NOTE 2:** Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.
Customer	Organization or person that receives a product; EXAMPLES: Consumer, researcher, client, or end user. **NOTE 1:** A customer can be internal or external to the organization. **NOTE 2:** Employees may be regarded as internal customers.
Derivative	The original characteristics of the specimen are changed (FFPE vs DNA derived from FFPE).
Deviation	A change from what is usual or expected. Deviations can apply to any documented policy, process or procedure as well as behavior.
Document	Information and its supporting medium; **NOTE:** This may be paper-based or electronic. Examples include Standard Operating Procedures and Pathology Reports.
Error	A deviation from truth, accuracy, or correctness; a mistake.
Failure	In the broadest sense, a case when the system does not meet user or customer expectations; **NOTE:** This includes the inability to perform its intended functions satisfactorily or within specified performance limits.
Form	A paper or electronic document on which information or results are captured; **NOTE:** Once completed, a form becomes a record.
Objective	Planning element that delineates in detail how to accomplish a specific goal at the process level.
Preventative Action	Action to prevent the cause of a potential **nonconformity** or other undesirable potential situation.

Policy	A documented statement of overall intentions and directions defined by those in the organization and endorsed by management.
Procedure	Specified way to carry out an activity of a process. A procedure is a set of instructions that describes the stepwise actions taken to complete activities identified in processes.
Process	Set of interrelated or interacting activities that transform input into outputs.
Quality System Essentials	Management foundation of interrelated processes that support the laboratory's path of workflow for quality management.
RBR	Regional Biorepository
Record	Document stating results achieved or providing evidence of activities performed. Some examples include freezer logs, incident reports, the master equipment file, etc.
Sample	This is an aliquot, derivative or if the Parent Specimen received is stored as a whole specimen, it is referred to as a sample, as per ACSR database definition.
SOP	Standard Operating Procedure. A set of written instructions that document a routine or repetitive activity followed by an organization.
Specimen	The same as Biospecimen. Human material such as urine, blood, tissue stored in a biorepository for use in laboratory research. For the ACSR this is considered the original or parent biospecimen/ specimen.
Validation	Confirmation through the provision of objective evidence that the requirements for a specific intended use or application have been fulfilled; **NOTE:** Examples include validation of the process to use a new diagnostic tool, such as an automated laboratory test system or information system; or evidence-based medicine.

5.0 ROLES AND RESPONSIBILITIES

This SOP applies to all personnel from ACSR RBRs and affiliates that are responsible for the processing of biospecimens for storage.

ACSR Personnel	**Responsibility/Role**
ACSR staff member	Process biospecimen, label vials, perform data entry and record storage.

6.0 MATERIALS, EQUIPMENT AND FORMS

Materials and Equipment	**Materials and Equipment (Site Specific or equivalent)**
Biospecimen/ Processing Form	
PPE – gloves	Kimberly-Clark Purple Nitrile gloves:Fisher Scientific catalog #19-149-863B
PPE – splash shield	Splash shield: Fisher Scientific catalog #17-310
PPE – lab jacket	Kleenguard disposable lab jackets or Kleenguard disposable sleeves: Fisher Scientific catalog #17-981-41G and Fisher Scientific catalog #17-981-41D
10% Bleach solution	
70% ethanol solution	
Kim wipes	
Level 2 Biosafety Cabinet/ Laminar flow hood	

7.0 PROCEDURES

This procedure is intended to ensure that biospecimens are processed and stored in a safe and efficient manner while eliminating the risks of contamination and loss.

7.1 Special Safety Precautions

7.1.1 Comply with "Universal Precautions" when handling all biospecimens.

7.1.2 Use PPE (personal protective equipment) in accordance with the institution's guidelines.

7.1.3 Standard best-practice working procedures include careful manipulation of the patient biospecimens, disinfection of countertops and equipment used during testing, and disposal of biohazard waste into appropriate receptacles.

7.2 Verification of Identification Information on Biospecimen Vessel

As applicable, verify the accuracy of coded patient information (in keeping with privacy and ethical policies) and ensure that it corresponds with the information on labels on Biospecimen and Biospecimen vessel or tube. Ensure that all personnel are trained in the use of the ACSR database and local electronic information system(s).

7.3 Upon receipt of a blood/serum/ascites biospecimen:

7.3.1 Be sure to remove draw sheet/forms from the transport container and place biospecimen in hood until ready for processing.

7.3.2 Assign an ACSR accession number or biobank identifier and use to label all processed biospecimens for storage.

7.3.3 Processing is conducted in biohazard room in the biological safety cabinet level 2 (BSL2)/ laminar flow hood. Handle all biospecimens as if infectious material. Wear appropriate PPE before the specimen is handled in any way: Gloves, laboratory coat, sleeves, face shield/goggles, face mask.

7.3.4 Process biospecimens as per the standard operating procedure.

7.3.5 After processing label specimen appropriately, if the biospecimen is to be frozen, put the biospecimen in either the controlled rate freezer or the −80°C holding box until the temperature is brought down to be transferred to Liquid Nitrogen taking extra care to secure the tubes. Record the storage location.

7.3.6 After processing, if the biospecimen is to be used in flow cytometric assays, be sure that the fixing solution is added and that the biospecimen is vortexed prior to departure from the biohazard room.

7.3.7 Make sure to dispose of any materials used in the processing of these biospecimens in the red biohazard bags and/or in the sharps containers.

7.3.8 Anything that has had an unfixed bodily fluid should be treated with bleach (10% of volume) prior for 10 minutes to dumping into red bag.

7.3.9 Sleeves should be used for disposal of the serological pipettes or designated pipet disposal covered container. The laminar flow hood (BSL2) should be swiped down with 10%bleach solution and 70%ethanol.

7.4 Upon Receipt of Tissue/Biopsy Biospecimens:

7.4.1 Be sure to remove draw sheet/forms from the transport container and place biospecimen in hood until ready for processing.

7.4.2 Assign an ACSR accession number or biobank identifier and use to label all processed biospecimens for freezing.

7.4.3 Processing is conducted in biohazard room in the biological safety cabinet level 2/ laminar flow hood. Handle all biospecimens as if infectious material. Wear appropriate PPE before the specimen is handled in any way: Gloves, laboratory coat, sleeves, face shield/goggles, face mask.

7.4.4 Process biospecimens as per standard operating procedure. Label appropriately biospecimen, aliquots, derivatives and record storage location. If cutting is involved, take extra care with any fresh material and be sure to do all work in a laminar flow hood (BSL2).

7.4.5 Make sure to dispose of any waste in a red biohazard bag. The laminar flow hood should be swiped down with 10%bleach solution and 70%ethanol.

7.5 Record data

7.5.1 Data should be recorded at the time of biospecimen acquisition or as soon as possible thereafter.

7.5.2 Data may be documented electronically at the time of collection or on paper and then entered into a database at a later time.

7.5.3 Paper documents (biospecimen forms) containing patient health information are stored in a locked room in a locked cabinet or scanned and saved electronically on a secure drive.

7.5.4 Electronic data is secured through institutional firewalls and password protected.

7.5.5 Electronic data may be entered into the ACSR database or formatted in excel and uploaded to ACSR database at regular intervals.

8.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

8.1 NCI Best Practices for Biospecimen Resources
http://biospecimen.cancer.gov/practices/default.asp

8.2 Declaration of Helsinki
http://www.wma.net/en/30publications/10polices/b3/index.html

8.3 ISBER Best Practices: Recommendations for Repositories, Fourth Edition Campbell LD, Astrin JJ, DeSouza Y, Giri, J, Patel AA, Rawley-Payne M, Rush A and Sieffert N. The 2018 Revision of the ISBER Best Practices: Summary of Changes and the Editorial Team's Development Process. Biopreservation and Biobanking 16(1): 3-6. https://doi.org/10.1089/bio.2018.0001

8.4 US National Biospecimen Network Blueprint
http://biospecimens.cancer.gov/resources/publications/reports/nbn.asp

8.5 National Bioethics Advisory Commission: Research involving human biological materials: Ethical issues and policy guidance, Vol.1: Report and recommendations of the National Bioethics Advisory Committee. August 1999.
http://bioethics.georgetown.edu/nbac/hbm.pdf

9.0 APPENDICES

Not applicable.

10.0 REVISION HISTORY

SOP Number	Date revised	Author	Summary of Revisions
Tech009	3-28-2018	RH	Replace sample with biospecimen, formatting.
